

REMARKS

Claims 1-4, 6-27, 29-30, and 35-37, are pending in the above-identified application. Claims 5, 28, and 31-34, have been canceled without prejudice or disclaimer. Claims 20 and 26 have been amended to recite the step of "sonicating." Claims 4, 8, and 9, have been rewritten in independent form as new claims 35, 36, and 37. Claim 1 has been amended to correct a typographical error. No new matter has been added.

I. At Page 2 of the Office Action, claims 1-3, 7, 18, and 19, have been rejected under 35 USC § 102(b) as being anticipated by Elledge et al.

The Examiner states that Elledge et al. disclose a method for producing a cleaned tissue graft by sonicating the tissue graft with detergents. The Examiner points to col. 3, lines 45-60, of Elledge et al. in support of her position. A brief analysis of Elledge et al. is set forth below.

Elledge et al. disclose at col. 3, lines 45-60, that an object of the invention is to provide a system for the sterile preparation of transplantable tissue. The operation of this "system" is discussed at cols. 7 and 8. Col. 7, lines 15-20 disclose that the cleaning process is a two-stage process requiring a first "high pressure sterile jet cleaning process" and an optional second "sterile ultrasonic bath cleaning process." Elledge et al. disclose cleaning bone segments only. First, the bone segments are extracted and are preliminarily cleaned to remove the soft tissue from the bone segment. See col. 7, lines 22-23. Thereafter, the segment is cleaned using the high pressure jet cleaning process. See col. 7, lines 23-49. At that point a determination is made whether to continue the cleaning process using the ultrasonic cleaning process, or to use the already cleaned bone segment. See col. 7, lines 49-50. If the ultrasonic process is used, the cleaned bone segment free from soft tissue is further cleaned and then sonicated. See col. 7, lines 50-58. Elledge discloses at col. 8, lines 1-5, that the bone segment after cleaning is free from particles. See also figs. 10 and 11. These figures illustrate a bone segment not only free from soft tissue, but also free from particulate matter.

Present claim 1 requires sonicating a soft tissue graft and requires the production of a soft tissue graft essentially free from blood deposits. Anticipation under 35 USC §102 requires that a single prior art reference disclose each and every element of the claimed invention. Elledge et al. do not disclose cleaning a soft tissue graft. Elledge et al. do not teach producing a cleaned soft tissue graft. Accordingly, it is submitted that Elledge et al. do not teach each and every element of claim 1 as required for anticipation under 35 USC §102.

Claim 2 requires a soft tissue graft essentially free from blood deposits, bacteria particles, virus particles and fungus particles. Again, Elledge et al. do not disclose cleaning a soft tissue graft. Further, Elledge et al. do not teach producing a cleaned soft tissue graft. Accordingly, it is submitted that Elledge et al. do not teach each and every element of claim 1 as required for anticipation under 35 USC §102.

Claim 3 requires a cleaned soft tissue graft produced by sonicating the soft tissue with a solvent. Elledge et al. do not disclose cleaning a soft tissue graft. Further, Elledge et al. do not teach producing a cleaned soft tissue graft. Accordingly, it is submitted that Elledge et al. do not teach each and every element of claim 1 as required for anticipation under 35 USC §102.

Claim 7 requires producing a first cleaned soft tissue graft optionally attached to bone where the graft is cleaned by sonication with a solvent. Elledge et al. do not disclose cleaning a soft tissue graft using sonication. Elledge et al. teach only cleaning a bone graft *from which the soft tissue has been removed*. Elledge et al. do not teach producing a cleaned soft tissue graft. Accordingly, it is submitted that Elledge et al. do not teach each and every element of claim 1 as required for anticipation under 35 USC §102.

Claims 18 and 19, are dependent upon the above claims and disclose particular soft tissue grafts.

In view of the above arguments, it is submitted that Elledge et al. do not disclose each and every element of the claimed invention as required for anticipation under 35 USC §102. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

II. At Page 2 , of the Office Action, claims 20-34 have been rejected under 35 USC §102 as being anticipated by Livesey et al.

The Examiner states that Livesey et al. disclose a method for cleaning soft tissue with detergents and incubation. The Examiner points to col. 9, lines 37-55 in support of her position.

Claims 20 and 26 have been amended to require the step of sonicating the soft tissue graft. Support for this amendment appears throughout the specification and claims as originally filed.

Livesey et al. do not teach sonicating a soft tissue graft in a bone cleaning composition as required by claims 20-26. It is submitted that Livesey et al. do not anticipate claims 20-26 as amended, since Livesey et al. do not teach each and every element of claims 20-26, as required for anticipation under 35 USC §102.

Claims 27, 29 and 30 are dependent on claims 1, 6, and 7, respectively. Claims 1, 6, and 7, all require sonicating the soft tissue in a solvent. Again, Livesey et al. do not teach sonicating a soft tissue graft in a solvent as required by claims 1, 6, and 7. It is submitted that Livesey et al. do not anticipate claims 27, 29, and 30, since Livesey et al. do not teach each and every element of claims 27, 29, and 30, as required for anticipation under 35 USC §102.

Claim 28 has been canceled without prejudice or disclaimer.

In view of the above arguments and amendments to the claims, it is submitted that Livesey et al. do not disclose each and every element of the claimed invention as required for anticipation under 35 USC §102. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At Pages 2 and 3 of the Office Action, claims 2, 5, and 6 have been rejected under 35 USC §102(e) as being anticipated by Morse et al. ('626).

The Examiner states that the '626 discloses a method for removing bone marrow whereby a high pressure solvent is introduced into the bone that inactivates bacteria, fungi, virus and parasites, where negative pressure is applied in a vacuum at less than atmospheric pressure to remove bone marrow.

Present claim 2 requires a soft tissue graft which is essentially free from blood deposits, bacteria particles, virus particles and fungi. '626 does not teach producing soft tissue grafts. '626

is directed to the preparation of bone *only*, for transplantation. Thus, as to claim 2, it is submitted that '626 does not teach each and every element of claim 2, as required for anticipation under 35 USC §102(e).

Claim 5 has been canceled without prejudice or disclaimer. Regarding claim 6, claim 6 requires the step of "...sonicating said essentially intact bone graft and associated soft tissue in a container with said first solvent using an ultrasonic cleaner,...said inducing and said sonicating are carried out simultaneously for" Again, '626 does not teach producing soft tissue grafts. '626 is directed to the preparation of bone *only*, for transplantation. Further, '626 does not teach cleaning either a soft tissue graft or a bone graft using sonication, as required by present claim 6. Thus, as to claim 6, it is submitted that '626 does not teach each and every element of claim 6, as required for anticipation under 35 USC §102(e).

In view of the above arguments, it is submitted that '626 does not disclose each and every element of the claimed invention as required for anticipation under 35 USC §102. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At Page 3, of the Office Action, claims 1-19 have been provisionally rejected under the judicially created doctrine of double patenting over the claims of copending application nos: 08/646,519 and 08/646,203.

Responsive to this rejection, a terminal disclaimer will be filed in this case upon an indication of allowance.

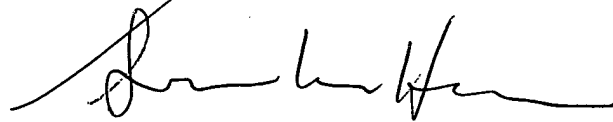
V. At Page 3, of the Office Action, the Examiner indicates claims 4 and 8-17, allowable if rewritten in independent form.

The Examiner is thanked for indicating claims 4 and 8-17 allowable if rewritten in independent form. Accordingly, claims 4, 8 and 9, have been rewritten in independent form as new claims 35, 36, and 37. It is submitted that claims 35, 36, and 37, are in condition for immediate allowance.

In view of the above, it is respectfully submitted that claims 1-4, 6-27, 29-30, and 35-37, are in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is respectfully requested to contact the undersigned on any questions that may arise.

Respectfully submitted,

SUSANNE M. HOPKINS, LIFE NET



Susanne M. Hopkins
Attorney for Applicant
Registration No. 33,247

Date: July 7, 1999

SUSANNE M. HOPKINS, ESQ.

LIFE NET

5809 Ward Court

Virginia Beach, Virginia 23455

Phone: (757) 464-4761

Fax: (757) 464-5721